

S.M.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,416	12/10/2001	Cynthia C. Barndad	A-67032-2/RFT/RMS/RMK	1226

7590 03/10/2004

Robin M. Silva
FLEHR HOHBACH TEST ALBRITTON & HERBERT LLP
Suite 3400
Four Embarcadero Center
San Francisco, CA 94111-4187

EXAMINER

LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
----------	--------------

1634

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/016,416

Applicant(s)

BAMDAD ET AL.

Examiner

Frank W Lu

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,20-27,36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,20-25,27,36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 18 and 20-27, and species (1) (claims 24 and 25) filed on November 24, 2003 is acknowledged. Note that applicant change "claims" to "claim 18" in claims 20, 22-24, 26, and 27 of the response filed on November 24, 2003 is unnecessary because, in fact, claims 20, 22-24, 26, and 27 in applicant's amendment filed on July 10, 2003 have comprised a phrase "claim 18" and have not contained the word "claims" (see applicant's amendment filed on July 10, 2003). Rejection and/or objection not reiterated from the previous first office action mailed on March 11, 2003 are hereby withdrawn in view of applicant's response filed on July 10, 2003. Since applicant adds new claims 36 and 37 and cancels claims 19 and 28-35, claims 18, 20-25, 27, 36, and 37 will be examined.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 24 recites the limitation "said ETM" in the claim. There is insufficient antecedent basis for this limitation in the claim since there is no ETM in claim 18. Please clarify.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 18, 27, 36, and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Heller *et al.*, (US Patent No. 6,652,808, filed on December 6, 1996).

Heller *et al.*, teach methods for the electronic assembly and fabrication of devices.

Regarding claims 18, 27, and 36, since Heller *et al.*, teach first microscale or nanoscale component devices including at least a first specific DNA polymer sequence thereon and a non-nucleic acid component wherein the first component devices are nanobeads or nanoparticles (see columns 26-28, column 41, claim 102, column 42, claims 121-123, Figures 37-40), Heller *et al.*, disclose a plurality of colloids (ie., nanobeads or nanoparticles) wherein each colloid comprises a binding ligand partner or a second nucleic acid (ie., at least a first specific DNA polymer sequence) as recited in b) of claims 18 and 36, and claim 27. Since Heller *et al.*, teach that the nanobeads or nanoparticles are fluorescent nanospheres (see column 28, second paragraph), the nanobeads or nanoparticles taught by Heller *et al.*, must be labeled with a fluorescent dye. The specification defines “electron transfer moiety” as molecules capable of electron transfer under certain conditions (see the specification, page 50, six paragraph). Since it is known in the art that the activation of a fluorescent dye includes electron transfer, according to the definition of the specification, the fluorescent dye on the nanobeads or nanoparticles taught by Heller *et al.*, is an

Art Unit: 1634

electron transfer moiety as recited in b) of claim 18. Since Heller *et al.*, teach a microelectronic array containing nucleic acid sequences that are complementary to at least first specific DNA polymer sequence and are immobilized on 64 microelectrodes (see column 27, lines 33-52 and Figures 37 and 38), Heller *et al.*, disclose an array of electrodes wherein each electrode comprises a binding ligand or a first nucleic acid (ie., nucleic acid sequences that are complementary to at least first specific DNA polymer sequence and are immobilized on 64 microelectrodes) as recited in a) of claims 18 and 36, and claim 27. Since Heller *et al.*, teach that microelectronic array is built in silicon (see column 28, last paragraph) and, as shown above, Heller *et al.*, teach an array of electrodes and a plurality of colloids, Heller *et al.*, disclose a composition comprising a substrate (ie., silicon) as recited in claims 18 and 36.

Regarding claim 37, since Heller *et al.*, teach avalanche photo diode array detector (see Figure 45), Heller *et al.*, disclose a detector as recited in claim 37.

Therefore, Heller *et al.*, teach all limitations recited in claims 18, 27, 36, and 37.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

Art Unit: 1634

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller *et al.*, (December 6, 1996) as applied to claims 18, 27, 36, and 37 above, and further in view of Sigal *et al.*, (US Patent No. 6,319,670 B1, filed on December 23, 1997).

The teachings of Heller *et al.*, have been summarized previously, *supra*.

Heller *et al.*, do not disclose that said plurality of colloids comprises a self-assembled monolayer wherein said self-assembling monolayer comprises an alkyl chain recited in claims 20 and 21.

Sigal *et al.*, teach that method and apparatus for improved luminescence assays using microparticles.

Regarding claims 21 and 22, Sigal *et al.*, teach microparticles (ie., colloidal gold particles) comprised of an electrically conductive material having (a) one or more copies of an array-ligand immobilized on its outsurface and (b) a plurality of electrochemiluminescent moieties immobilized on its outsurface (see column 4, lines 40-67). Since Sigal *et al.*, teach that the array-ligands are coated the particle to form a self-assembled monolayer (see column 8, second paragraph), Sigal *et al.*, disclose said plurality of colloids comprises a self-assembled monolayer as recited in claim 20. Since the array-ligands taught by Sigal *et al.*, can be amino acids (see column 3, lines 19-56) and it is known that some amino acid such as lysine have two

Art Unit: 1634

or more CH₂ groups (alkyl groups), Sigal *et al.*, disclose that said self-assembling monolayer comprises an alkyl chain as recited in claim 21.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have coated said plurality of colloids recited in claim 18 with array-ligands (ie., amino acids), each comprising an alkyl chain such as lysine, and formed a self-assembled monolayer of the array-ligands as recited in claims 20 and 21 in view of the patents of Heller *et al.*, and Sigal *et al.*. One having ordinary skill in the art would have been motivated to do so because the colloids coated with positive charged lysine would reduce non-specific binding of the colloids and prevent aggregation of the colloids (see column 6, lines 39-60), and promote the colloids to act as electrodes in an electrochemiluminescent assay (see column 8, second paragraph). One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to coat said plurality of colloids recited in claim 18 with array-ligands (ie., amino acids), each comprising an alkyl chain such as lysine in order to form a self-assembled monolayer as recited in claims 20 and 21.

9. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heller *et al.*, (December 6, 1996) as applied to claims 18, 27, 36, and 37 above, and further in view of Henkens *et al.*, (US Patent No. 6,391,558, priority date: March 17, 1997).

The teachings of Heller *et al.*, have been summarized previously, *supra*.

Heller *et al.*, do not disclose that said substrate is a printed circuit board.

Henkens *et al.*, teach that a plurality of working and reference electrodes of a biosensor

Art Unit: 1634

array are comprised on a printed circuit board wherein a plurality of labeled nucleic acid segments are attached to the working electrodes (see column 4, last paragraph).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a composition as recited in claim 18 wherein said substrate is a printed circuit board as recited in claim 22 in view of the patents of Heller *et al.*, and Henkens *et al.*. One having ordinary skill in the art would have been motivated to do so because Henkens *et al.*, have successfully made a array of electrodes with a plurality of binding ligands (ie., labeled nucleic acid segments) and the simple replacement of one kind of substrate (ie., a substrate taught by Heller *et al.*,) from another kind of substrate (ie., a printed circuit board taught by Henkens *et al.*,) during the process of making a composition recited in claim 22 would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made because the replacement would not change the composition of claim 18.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Art Unit: 1634

10. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heller *et al.*, (December 6, 1996) as applied to claims 18, 27, 36, and 37 above, and further in view of Kayyem *et al.*, (US Patent No. 6,096,273, filed on November 5, 1996).

The teachings of Heller *et al.*, have been summarized previously, *supra*.

Heller *et al.*, do not disclose that said electrodes are gold as recited in claim 23.

Kayyem *et al.*, teach to covalently attach nucleic acids (ie., binding ligands as recited in claim 18) to an electrode such as a gold electrode. The different electrodes are used and these electrodes are exchangeable (see column 20, lines 40-65).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a composition as recited in claim 18 wherein said electrodes are gold as recited in claim 23 in view of the patents of Heller *et al.*, and Kayyem *et al.*. One having ordinary skill in the art would have been motivated to do so because Kayyem *et al.*, have successfully attached nucleic acids to gold electrodes and suggest that electrodes are exchangeable (see column 20, lines 40-65), and the simple replacement of one kind of electrode (ie., electrodes taught by Heller *et al.*,) from another kind of electron transfer moiety (ie., gold electrodes taught by Kayyem *et al.*,) during the process of making a composition recited in claim 23 would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made because the replacement would not change the composition of claim 18.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their

Art Unit: 1634

expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

11. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heller *et al.*, (December 6, 1996) as applied to claims 18, 27, 36, and 37 above, and further in view of Sigal *et al.*, (December 23, 1997).

The teachings of Heller *et al.*, have been summarized previously, *supra*.

Heller *et al.*, do not disclose that said electron transfer moiety (ETM) is a transition metal complex as recited in claim 24.

Sigal *et al.*, teach microparticles (ie., colloidal gold particles) comprised of an electrically conductive material having (a) one or more copies of an array-ligand immobilized on its outsurface and (b) a plurality of electrochemiluminescent moieties immobilized on its outsurface (see column 4, lines 40-67) wherein electrochemiluminescent moieties are transition metal complexes (see column 9, first paragraph).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a plurality of colloids comprising electron transfer moieties as recited in claim 18 wherein the electron transfer moieties are transition metal complexes as recited in claim 24 in view of the patents of Heller *et al.*, and Sigal *et al.*. One having ordinary skill in the art would have been motivated to do so because Sigal *et al.*, have

Art Unit: 1634

successfully made colloids comprising electron transfer moieties wherein the electron transfer moieties are transition metal complexes and the simple replacement of one kind of electron transfer moiety (ie., a fluorescent dye taught by Heller *et al.*,) from another kind of electron transfer moiety (ie., a transition metal complex taught by Sigal *et al.*,) during the process of making a composition recited in claim 24 would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made because the replacement would not change the composition of claim 18.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

12. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heller *et al.*, (December 6, 1996) as applied to claims 18, 27, 36, and 37 above, further in view of Sigal *et al.*, (December 23, 1997) as applied to claims 20, 21, and 24 above, and further in view of Kayyem *et al.*, (November 5, 1996).

The teachings of Heller *et al.*, and Sigal *et al.*, have been summarized previously, *supra*.

Heller *et al.*, and Sigal *et al.*, do not disclose that said transition metal complex is ferrocene as recited in claim 25.

Art Unit: 1634

Kayyem *et al.*, teach that electron transfer moieties are different transition metal complexes such as ferrocene. These different transition metal complexes are exchangeable (see column 29, lines 31-42).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a composition recited in claim 24 wherein said transition metal complex is ferrocene in view of the patents of Heller *et al.*, Sigal *et al.*, and Kayyem *et al.*. One having ordinary skill in the art would have been motivated to do so because Kayyem *et al.*, have used ferrocene as an electron transfer moiety and suggests that electron transfer moieties are exchangeable (see column 29, lines 31-42), and the simple replacement of one kind of transition metal complex (ie., a transition metal complex taught by Sigal *et al.*,) from another kind of transition metal complex (ie., a transition metal complex such as ferrocene taught by Kayyem *et al.*,) as an electron transfer moiety during the process of making a composition recited in claim 25 would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made because the replacement would not change the composition of claim 24.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. No claim is allowed.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Art Unit: 1634


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746.

The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
March 1, 2004



**BJ FORMAN, PH.D.
PRIMARY EXAMINER**